

# Collaborative randomised controlled trial of trigger versus conventional ventilation in preterm infants with respiratory distress syndrome

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/10/2014	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Harry Baumer

**Contact details**  
Plymouth Hospitals NHS Trust  
Derriford Hospital  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH  
+44 (0)1752 763450  
harry.baumer@phnt.swest.nhs.uk

## Additional identifiers

**Protocol serial number**  
C/6/16-04-94/BAUMER/F

## Study information

## Scientific Title

### Study objectives

Objectives: To investigate the effects of Patient Triggered Ventilation (PTV) compared with conventional ventilation (Intermittent Mandatory Ventilation [IMV]) in preterm infants ventilated for Respiratory Distress Syndrome (RDS).

Setting: Twenty-two neonatal intensive care units.

Design: Subjects were 924 babies under 32 weeks gestation and within 72 hours of birth ventilated for RDS for less than 6 hours. Telephone randomisation to receive either PTV or IMV. Analysis on "intention to treat" basis.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Neonatal diseases

### Interventions

1. Trigger ventilation
2. Conventional ventilation

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome(s)

1. Death before discharge home or oxygen therapy at 36 weeks gestation
2. Pneumothorax whilst ventilated
3. Cerebral ultrasound abnormality nearest 6 weeks
4. Duration of ventilation in survivors

### Key secondary outcome(s)

Not provided at time of registration

**Completion date**

31/03/1998

## Eligibility

**Key inclusion criteria**

Infants of less than 32 weeks gestation, they are ventilated within 72 hours of birth, and have features compatible with respiratory distress syndrome

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

Babies with evidence of major congenital malformation or evidence of inhalational pneumonitis will be excluded

**Date of first enrolment**

01/11/1994

**Date of final enrolment**

31/03/1998

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Plymouth Hospitals NHS Trust

Plymouth

United Kingdom

PL6 8DH

## Sponsor information

## Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

## Funder(s)

### Funder type

Government

### Funder Name

NHS Executive South West (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2000		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes